REMARKS

Claims 1 – 5, 7 – 14 and 16 – 19 are pending in the present application. Claim 1 has been amended to exist as a kit claim. Claims 2 and 17 – 19 have been amended to provide for the proper antecedent support.

Support for the amendment to Claim 1 can be found in the specification on pages 4, lines 9 – 10, where it states that any sol-gel material may be used for the micro-valving according to the present invention. Claims 1 – 5, 7 – 14 and 16 – 19 remain for consideration upon entry of the present remarks.

Claim Rejections Under 35 U.S.C. §102(b)

Claims 1, 2, and 17-19 are rejected under 35 U.S.C. §102(a), (b) or (e) as being allegedly anticipated by Stern. U.S. Patent Application Publication No. 2002/0119536 (hereinafter "Stern"). (See Office Action dated 07-18-2011, page 3)

To anticipate a claim under 35 U.S.C. § 102, a single source must contain all of the elements of the claim. *Lewmar Marine Inc. v. Barient, Inc.*, 827 F.2d 744, 747, 3 U.S.P.Q.2d 1766, 1768 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1007 (1988).

Claim 1 is directed to a kit comprising a PCR (polymerase chain reaction) device and a sol-gel material for use in the PCR device, wherein the PCR device comprises an inlet through which a biochemical fluid is injected; an outlet through which the biochemical fluid is discharged; a PCR channel positioned between the inlet and the outlet; a heat source for operating the PCR device; and first and second micro-valves which is formed as channel for containing a sol-gel transformable material, wherein the first and second micro-valves control opening and closing of the inlet and the outlet, and intersect portions of the PCR channel near the inlet and the outlet of the PCR device, respectively; wherein the PCR channel extends in a first direction on a plane and the first and second micro-valves extend in a second direction on the plane of the PCR channel, the first direction and the second direction being perpendicular to each other, wherein the sol-gel material is for use in the first and second micro-valves; wherein the sol-gel transformable material transforms from a sol state into a gel state at a temperature lower than DNA denaturation temperature, annealing temperature and extension temperature and higher than room temperature, as the temperature increases to operate the PCR by the heat

source; and is operative to control the opening and closing of the first and second micro-valves; wherein an additional heat source for controlling the temperature of the sol-gel transformable material is absent from the PCR device; and wherein an additional valve means for the inlet and the outlet other than the first and second micro-valves is absent.

The invention of Claim 1 has first and second micro-valves which are formed as channels intersecting the PCR channel. The PCR channel extends in a first direction and the first and second micro-valves extend in a second direction. The first and second directions are on the same plane and the second direction is perpendicular to the first direction. The device is also provided with a sol-gel material that can be used in the first and second microvalves.

The micro-valves use a sol gel material to open and close by virtue of the temperature of the valves. The device operates on a biochemical fluid and not on the sol gel material, which is only used to open and close the valves.

With regard to the Figure 2 Stern teaches that:

> the reaction channel 110 intersects and is in fluid communication with two large electrical access channels, 150 and 160 respectively, at intersections 170 and 180. A transverse channel 140, for introducing polymerase, is in fluid communication with the reaction channel 110 and intersects it at intersection 190. The electrical access channels 150 and 160 are in fluid communication with filled reservoirs 200, and flow an electrical current into the reaction channel between the intersections 170 and 180. Each of the reservoirs 200 is partially filled with a matrix. The electrical resistance of the electrical access channels 150 and 160 is less than the electrical resistance of the reaction channel 110. The heating region of the reaction channel is defined by intersections 170 and 180, and is typically 20 mm long and 15 μm deep. The reaction mixture slugs are introduced into the reaction channel via a sample loading source. Upon entering the heating region 100, each reaction mixture slug undergoes a series of amplification cycles as it travels through the region.

(See Figure 2; see also paragraph [0066]) Stern thus teaches perpendicular channels 150 and 160 that can be heated to heat up a reaction mixture slugs. The reaction mixture slugs are being worked upon heat in the channels of Stern. Stern does not teach the use of valves for controlling the slug nor does it teach providing a sol gel material that can be used in the valves when desired to control the flow of fluids through the channel.

The claimed invention in contrast is directed to a PCR device that works on a biochemical fluid and contains valves that use a sol gel material to control flow of the

biochemical fluid. The claimed invention is also directed to a sol gel material for use in the microvalves. Stern does not teach that a sol gel material is provided for use with the device. For this reason at least, Stern does not teach all elements of the claimed invention and cannot anticipate the claimed invention.

The Applicants would now like to provide arguments as to how the kit claim defines over Stern.

The Examiner has alleged that "Stern is structurally capable of being used with a sol gel material and that "[E]xpressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability to the claims" (See page 3 of the Office Action)

The Applicants respectfully disagree. In the present invention, the Applicants are not working on the sol gel material. The Applicants are working on a chemical fluid whose flow is controlled using valves that make use of a sol gel material provided along with the device. The sol gel material does not serve the same purpose as the reactant slug of Stern. The chemical fluid in the claimed invention functions in much the same manner as the reactive slug of Stern.

In addition, it is submitted that the electrical access channels 150 and 160 of Stern are designed to provide heat to the fluid in the channel 100 through fluids that do not flow. (See paragraph [0048]) In other words, the electrical access channels must contain a fluid that does not flow but must be capable of transferring an electrical current to the channel 100 to cause the fluid (slug) in the channel 100 to flow. (See paragraph [0048]) Stern states that the material in the electrical channels must create high fluidic resistance and that it must be capable of transmitting an electrical current. (See paragraph [0048])

Stern identifies the material as a polyacrylamide gel. (See paragraph [0048]) Stern teaches that the "gel is accomplished by acing a polyacrylamide gel matrix to the reservoir 200 (see figure 2) in liquid form and polymerizing it to form a conformably fitting gel barrier to fluid flow. (See paragraph [0048]) The polymerized gel is then overlayered with a buffer. (See paragraph [0048])

Thus, even though a sol-gel material may be used in the channels 150 and 160, Stern does not desire it. Stern desires a permanently gelled material (a polymerized polyacrylamide) that can transmit an electrical signal and will not revert to a sol upon heating (if it did revert to a sol

then it would not be possible to overlay it with a buffer). The microvalves of the claimed invention in contrast use a sol-gel material that can transform from the gel state to the sol state upon heating. Stern's desire to avoid a material that can change phases (go from solid to liquid and vice versa) means that it would not provide a sol gel material with its device. It would also not desire a combination with another reference that teaches sol gel materials, since the use of a sol gel material militates against its desire to use a material that can create high fluidic resistance in the electrical channels.

Since Stern does not teach that a sol gel material is provided with its device and does not desire the provision of a sol gel material for use with its device, it does not teach all elements of the claimed invention. The Applicants respectfully request a withdrawal of the anticipation rejection and an allowance of the claims.

In the Advisory Action, the Examiner sustained the rejection on the grounds that the claims were directed to a device and not to a kit. (See page 2 of the Advisory Action dated 10-06-2011) The Applicants have accordingly amended the Claims 1, 2, 17, 18 and 19 to be directed to a kit that comprises the device and the sol gel material for use in the device.

The Applicants respectfully request a withdrawal of this rejection and an allowance of the claims.

Conclusion

In view of the foregoing, it is respectfully submitted that the instant application is in condition for allowance. Accordingly, it is respectfully requested that this application be allowed and a Notice of Allowance issued. If the Examiner believes that a telephone conference with Applicants' attorneys would be advantageous to the disposition of this case, the Examiner is cordially requested to telephone the undersigned.

In the event the Commissioner of Patents and Trademarks deems additional fees to be due in connection with this application, Applicants' attorney hereby authorizes that such fee be charged to Deposit Account No. 06-1130.

Respectfully submitted,

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